



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,738	11/20/2003	Hiroyuki Odaka	2596 US1P	8700
23115	7590	09/16/2005	EXAMINER	
TAKEDA PHARMACEUTICALS NORTH AMERICA, INC INTELLECTUAL PROPERTY DEPARTMENT 475 HALF DAY ROAD SUITE 500 LINCOLNSHIRE, IL 60069			WEDDINGTON, KEVIN E	
		ART UNIT	PAPER NUMBER	
		1614		
DATE MAILED: 09/16/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/717,738	ODAKA ET AL.
	Examiner	Art Unit
	Kevin E. Weddington	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 June 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 9-12, 16, 18, 24, 27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 9-12, 16, 18, 24, 27 and 28 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>1-20-05</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

Art Unit: 1614

Claims 9-12, 16, 18, 24, 27 and 28 are presented for examination.

Applicants' information disclosure statement filed January 20, 2005 and the amendment filed June 24, 2005 have been received and entered.

Accordingly, the rejection made under 35 USC 112, first paragraph as set forth in the previous Office action dated April 21, 2005 at pages 2-5 is hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-12, 16, 18, 24, 27 and 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for improving or treating diabetic acidosis and the acidosis is acidosis caused by a biguanide with an insulin sensitizer disclosed in claim 18, and a composition comprising an insulin sensitizer in combination with insulin disclosed in claim 16, does not reasonably provide enablement for treating disturbance of consciousness, coma or respiratory diseases with the insulin sensitizer or the instant composition as disclosed in claims 12 and 27. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to a method for improving or treating acidosis in a mammal in need thereof, which comprises administering to said mammal an effective amount of an insulin sensitizer selected from the group consisting of

- 1) pioglitazone or a salt thereof;
- 2) 5-[[6-(2-fluorobenzyl)oxy]-2-naphthyl]methyl]-2,4-thiazolidinedione;
- 3) CS-011;
- 4) BM-13-1258

or a combination of the above insulin sensitizer with insulin (claim 16).

The relative skill of those in the art is generally that of a Ph.D. or M.D.

The present invention is unpredictable unless experimentation is shown for the instant insulin sensitizers can treat disturbance of consciousness, coma or respiratory distress.

The breadth of the claims

The claims are very broad and inclusive to all causes of acidosis can be improved or treated with the instant insulin sensitizers.

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are limited to the administration of pioglitazone and its salts to treat acidosis, wherein the acidosis is caused by a biguanide (metformin)

No working example showing the administration of the instant insulin sensitizers of claims 16 and 18 will treat disturbance of consciousness, coma or respiratory distress.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to how the instant insulin sensitizers are effective in improving the disturbance of consciousness, coma or respiratory distress or the other causes of acidosis . The level of experimentation needed to determine the instant insulin sensitizers would be able to improve or to treat disturbance of consciousness, coma or respiratory distress and other causes of acidosis is undue. Therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

Claims 9-12, 16, 18, 24, 27 and 28 are not allowed.

To overcome this rejection, the applicants may wish to amend claim 18 by inserting the limitations of claims 10 and 11 into claim 18; and delete claim 12. Also the same recommendation for claim 16 by inserting the limitations of claims 10 and 11 into claim 16; and delete claim 27.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington

Application/Control Number: 10/717,738
Art Unit: 1614

Page 6

September 14, 2005